

Express Mail Label #EV 337979266 US

PATENT
Attorney Docket No.: 50623.00169REMARKS

Claims 1-4, 6-11, 16, 17, and 44-47 are pending in this application. The Applicants request cancellation of claims 5, 12, and 13. Amendments to claims 9 and 17 have been made to correct typographical errors. The Applicants gratefully acknowledge the Examiner's participation in an Interview on August 12, 2003. The numbered paragraphs below correspond to the Examiner's numbered paragraphs.

1.2. Claims 1-4, 6-11, 16, 17, and 44-47 stand rejected under 35 U.S.C. 112, first paragraph. As was discussed during the Examiner Interview, support for a bulk polymer phase being substantially or completely devoid of the drug can be found throughout the specification, notably at Page 4, lines 13-15 and 18-20. The Examiner's attention is drawn to the Applicant's discussion in the Interview of adding a drug to a blended solution of two mutually insoluble polymers as a means of achieving the claimed result. Further, as was discussed in the Interview, support for a first polymer and a second polymer, with the second polymer being significantly or completely insoluble in the first polymer can also be found throughout the specification, notably at Page 4, line 25. Withdrawal of the rejection is respectfully requested.

3. Claims 1, 2, 4, 10, 11, 17 and 44-47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Eury et al. (U.S. Patent No. 5,605,696). The Examiner noted in the Office Action dated May 14, 2003 that "the polymeric material can be considered a bulk polymer." Eury et al. teach that "[a] selected therapeutic drug is preferably intimately mixed with the selected polymeric material so as to uniformly disperse the therapeutic drug in the polymeric material" (col. 3, lines 26-29). As was discussed in the Interview, the polymeric material of Eury et al. is "intimately mixed" with the drug, which is distinctly different from Claim 1, which requires that "the bulk polymeric phase is substantially or completely devoid of the drug."

The Examiner further noted in the Office Action dated May 14, 2003 that "the drug and porosigen can be considered a drug-enriched phase." As was discussed in the Interview, the porosigen of Eury et al. is "leached out" leaving behind a "continuous drug loaded polymeric matrix" (Col. 15, lines 6-7). Thus, the system of Eury et al. is distinctly

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different from the drug release system of Claim 1, which requires "a drug incorporated into the drug-enriched phase" and that "the bulk polymeric phase is substantially or completely devoid of the drug." Accordingly, Claim 1 is patentably allowable over Eury et al. Claims 2, 4, 10, 11 and 17 depend directly from Claim 1 and are therefore patentably allowable for at least the same reason. Withdrawal of the rejection and allowance of the claims is respectfully requested.

4. Claims 1-4, 6-11, 16 and 17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Hossainy et al. (U.S. Patent No. 6,153,252). The Examiner noted in the Office Action dated May 14, 2003 that "the topcoat can be considered a bulk polymer, and the film-forming polymer a drug-enriched phase." As was discussed in the Interview, Hossainy et al. fail to teach the limitation of "a bulk polymer phase; a polymeric drug-enriched phase within the bulk polymer phase" as recited by Claim 1. The Examiner's attention is again drawn to Figures 1 and 2 for clarification of this point. Accordingly, Claim 1 is patentably allowable over Hossainy et al. Claims 2-4, 6-11, 16 and 17 depend directly and indirectly from Claim 1 and are allowable for at least the same reason. Withdrawal of the rejection and allowance of the claims is respectfully requested.

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Attorney Docket No.: 50623.00169**CONCLUSION**

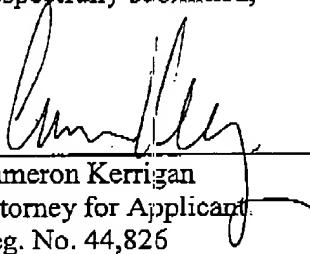
Claims 1-4, 6-11, 16, 17, and 44-47 are pending in this application.

Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0323.

Dated: August 29, 2003

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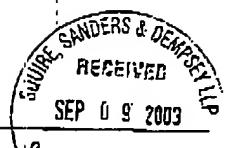
Respectfully submitted,


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Date Mailed: 08/29/03 | By: CKK/pg | Docket No.: 50623.169
 Serial No.: 09/822.952 | Filed: March 30, 2001

Applicant: Charles David Claude

Title: Controlled Morphologies In Polymer Drug For Release Of Drugs From Polymer Films



The following has been received in the U.S. Patent Office on the date stamped hereon:

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